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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,072	03/01/2002	Bozidar Ferek-Petric	P-8158.02 DIV1	1422

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EXAMINER	
OROPEZA, FRANCES P	

ART UNIT	PAPER NUMBER
3762	4

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,072	FEREK-PETRIC, BOZIDAR	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/1/02 (Initial Filing)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Domestic Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5188106) in view of Bardy (US 5314430) and further in view of Koestner et al..

Nappholz et al. disclose a multi-chamber cardiac assist or therapy device that senses atrial, ventricular and blood flow signals, analyzes the signals to detect a cardiac condition, and provides treatment in the form of pacing, defibrillation and drugs. The use of ultrasound/ blood

flow measurement alone, or the use of the electrocardiogram combined with the blood flow is taught to control the device (abstract; figures 1, 3, 8A, 9, 10; col. 4 @ 62-66; col. 5 @ 18-57; col. 13 @ 36-59; col. 14 @ 2-4 and 26-38; col. 16 @ 37-39 and 53-56; col. 18 @ 14-21; col. 18 @ 54 – col. 19 @ 20; col. 21 @ 43-61; col. 29 @ 25-43).

As discussed in the previous paragraph of this action, Nappholz et al. disclose the claimed invention except for the device comprising a coronary sensing means, and a programmer means.

As to the coronary sensing means, Bardy teaches lead system design using three sensing means including a coronary sinus means for the purpose of directly monitoring the cardiac activity in the left ventricle and optimizing defibrillation treatment. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a coronary sinus means in the Nappholz et al. system in order to provide the stimulation system with multiple electrode combinations so the stimulation treatment can be optimized based on the individual patient's needs (abstract; figure 1; col. 2 @ 37 – col. 3 @ 18; col. 6 @ 2-8 and 42-51).

As to the programmer means, Bardy teaches communicating with an implanted device using a programmer means for the purpose of defining and optimizing treatment therapies. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a programmer means in the modified Nappholz et al. system in order to provide the stimulation system with treatment flexibility so the treatment can be optimized based on the individual patient's needs (figure 3 - Telem; col. 9 @ 44-63).

As discussed in the previous four paragraphs of this action, modified Nappholz et al. disclose the claimed invention except for the blood flow sensing being on the coronary sinus means, and the blood flow rate signal being integrated.

As to the blood flow sensing means, Koestner et al. teaches blood flow monitor placement using positions on leads inside an outside the heart for the purpose of accurately measuring blood flow velocity. The teachings of the various positions of the blood flow monitor provide a clear suggestion that the position of the blood flow monitor can be modified to change the nature and quality of the recorded signal. The determination of the most appropriate placement of the blood flow monitor by routine experimentation should therefore, be prima facie obvious to one having ordinary skill in the blood flow monitoring art. Hence, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used blood flow monitor on one of the sensing means, the coronary sinus means, in the modified Nappholz et al. system in order to provide a signal collection site that affords a location for collecting an optimum, accurate, high quality blood flow signal (abstract; figures 1, 3, 7; col. 1 @ 9-16; col. 5 @ 46 – col. 6 @ 10).

As to the blood flow rate being integrated, Koestner et al. teach blood flow signal analysis using the signal analysis means to provide an integral of the blood flow signal for the purpose of focusing on the relevant parameter of the blood flow signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the signal analysis means to provide an integral of the blood flow signal in the modified Nappholz et al. system in order to optimize the quality of blood flow signal used to define and treat the cardiac condition (abstract; col. 25 @ 54 – col. 26 @ 15).

Drawings

4. Figures 4 and 5 are objected to under 37 CFR 1.83(a) because the reference numerals in the figures are in conflict with the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The follow objections are noted:

- Figure 4 appear to identify the indifferent electrode on the left ventricular pacing lead (41) to be electrode (21), but the specification uses reference numeral (24) to identify the indifferent electrode (specification – page 10, line 7). No reference numeral (21) associated with an electrode is found in the specification.
- Figure 5 and the specification identify reference numeral (15) as an electrode (specification – page 10, line 34), and the specification uses reference numeral (15) as indicating the electrode head (specification – page 9, lines 23-24).

Specification

5. The specification is objected to because:

- The reference numeral (24), associated with the indifferent electrode (specification – page 10, line 7) is not found in the drawings.
- Reference numeral (21), found in figure 4, is not found in the specification.
- The specification uses reference numeral (15) to identify an electrode (specification – page 10, line 34), and the specification uses reference numeral (15) to identify the electrode head (specification – page 9, lines 23-24).

- The flow sensor (22) (specification – page 11, line 21) is not indicated on figure 5.
- The flow sensor (24) (specification – page 12, line 21) is not found on figure 5, and it appears this reference numeral should be --(22)--.
- The time/control circuitry (63) (specification – page 13, line 7) is not found on figure 3, and it appears this reference numeral should be --(74)--.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frances P. Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached Monday through Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on (703) 308-5181.

The telephone number for facsimiles for regular communication and After Final communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
7/11/04

Angela D. Sykes

ANGELA D. SYKES
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